

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ALL CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**MEMORANDUM IN OPPOSITION TO
PLAINTIFFS' MOTION TO DETERMINE THE SUFFICIENCY OF
ETHICON, INC.'S AND JOHNSON & JOHNSON, INC.'S ANSWERS AND
OBEJCTIONS TO PLAINTIFFS' FIRST REQUESTS FOR ADMISSION**

Defendants submit this Memorandum in Opposition to Plaintiffs' Motion to Determine the Sufficiency of Ethicon, Inc.'s and Johnson & Johnson, Inc.'s Answers and Objections to Plaintiffs' First Requests for Admission [Doc. 1020]. Plaintiffs' motion was the first inkling Defendants had that Plaintiffs were dissatisfied with Defendants' RFA responses. In the absence of even an attempt to meet and confer, the Court should make quick work of this "tit for tat" motion¹ and deny it.

Background

On October 24, 2013, Plaintiffs' liaison counsel served their first set of Requests for Admissions on Defendants ("RFAs"). *See* Plaintiffs' Certificate of Service for First Requests for Admission to Defendants [Doc. 893]. These 221 RFAs included a large number of requests

¹ Defendants' filed a motion on January 9 setting out deficiencies with Plaintiffs' responses to Defendants' RFAs and asking that those RFAs be deemed admitted. Defendants, however, previously had written Plaintiffs with concerns about Plaintiffs' objections and also had engaged in a telephonic meet and confer. Plaintiffs' filed this motion – without any previous communication – later in the day on January 9.

addressing highly technical, scientific and medical subjects – but also using imprecise, undefined terms.

Defendants served their objections and answers on November 27, 2013. *See* Ex. A. Until Plaintiffs filed their Motion to Determine the Sufficiency of Defendants’ responses on January 9, 2014, there was no indication from Plaintiffs’ liaison counsel that they had any complaints with Defendants answers and objections to those RFAs. Indeed, Plaintiffs’ motion was filed with no Rule 37.1(b) certification of a meet and confer (because none occurred) and was filed *after* Defendants had, on the same day, filed their own motion regarding the deficiencies in Plaintiffs’ responses to Defendants’ Requests for Admissions.

None of Plaintiffs’ attacks on the sufficiency of Defendants’ RFA answers and objections have merit.

Legal Argument

I. Because Plaintiffs failed to comply with Local Civil Rule 37.1(b), their motion should be denied.

Local Civil Rule 37.1(b) requires the parties to meet and confer prior to filing discovery motions. *See* L.R. Civ. P. 37.1(b). “The purpose of the meet and confer obligation is to request and obtain discovery material *without court action*.” *Wilson v. Liberty Ins. Underwriters, Inc.*, 2008 U.S. Dist. LEXIS 39468, *5-6 (S.D. W. Va. May 15, 2008). Noticeably absent from Plaintiffs’ motion is any suggestion that a “meet and confer” transpired concerning Defendants’ answers and objections to the RFAs. The reason for this is simple: none occurred. Because Plaintiffs’ liaison counsel failed to make a good faith effort to resolve this dispute prior to filing their motion, it should be denied. *See id.* at *6-7.

II. Further, because Plaintiffs' motion is untimely, any objections they have to Defendants' answers and objections to the RFAs are waived.

Local Civil Rule 37.1(c) clearly states that “[m]otions to compel *or other motions in aid of discovery* not filed within 30 days after the discovery response or disclosure requirement was due are waived, and in no event provide an excuse, good cause or reason to delay trial or modify the scheduling order.” L.R. Civ. P. 37.1(c). Here, Defendants served their answers and objections to the RFAs in question on November 27, 2013;² however, Plaintiffs *waited forty-three (43) days* to file their motion to determine the sufficiency of those responses. Accordingly, Plaintiffs’ objections are waived and their motion should be denied.

III. Plaintiffs’ arguments against the sufficiency of Defendants’ answers and objections to the RFAs lack merit.

In determining the sufficiency of Defendants’ RFA responses, the Court “must consider the phraseology of the requests as carefully as that of the answers or objections.” *Thalheim v. Eberheim*, 124 F.R.D. 34, 35 (D. Conn. 1988). Indeed,

“each request for admissions must be direct, simple and ‘limited to singular relevant facts,’” . . . so that “it can be admitted or denied without explanation.” . . . A request “should not state ‘half a fact’ or ‘half-truths’ which require the answering party to qualify responses.”

Herrera v. Scully, 143 F.R.D. 545, 549 (S.D.N.Y. 1992) (quoting *Dubin v. E.F. Hutton Group Inc.*, 125 F.R.D. 372, 375-76 (S.D.N.Y. 1989) (internal citations omitted)). Plaintiffs’ requests are replete with such “half facts” and “half-truths.” “[Q]ualification is permitted if the statement, although containing some truth,’ . . . standing alone out of context of the whole truth . . . convey[s] unwarranted and unfair inferences.” *Diederich v. Dep’t of the Army*, 132 F.R.D. 614, 619 (S.D.N.Y. 1990) (quoting *Johnstone*, 25 F.R.D. at 44). This is certainly the case here.

² See Defendants’ Certificate of Service of Responses to First Requests for Admission to Defendants [Doc. 948].

Moreover, “[q]ualifying a response may be particularly appropriate if the request is sweeping, multi-part, *involves sharply contested issues, or goes to the heart of a defendant’s liability.*”

Wiwa v. Royal Dutch Petroleum, Co., 2009 U.S. Dist. LEXIS 45621, *17 (S.D.N.Y. May 26, 2009) (emphasis added).

A. Defendants’ responses fairly respond to the substance of Plaintiffs’ requests and any “qualifications” are made in good faith.

What is instructive about Plaintiffs’ RFAs is that the vast majority are not “direct” or “simple.” Plaintiffs’ requests do not ask Defendants to admit or deny that a document is a true and accurate copy;³ whether, after a date certain, defendant asked plaintiff to perform certain services;⁴ or whether defendant received a copy of certain documents.⁵ In layman’s terms, they are “loaded questions” presenting only partial truth for which good faith requires more than a simple “admit” or “deny” in response.

Plaintiffs first take issue with Defendants’ response to RFA No. 1:

REQUEST NO. 1: Admit that you never completed a controlled study involving live women with the actual TVT device (not a prototype) prior to marketing and selling the TVT in the U.S.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 1. Defendants admit that they did not complete a randomized controlled trial with the actual TVT device prior to marketing and selling the TVT in the United States, but Ethicon complied with FDA regulations and the 510(k) clearance process.

A simple “admit” or deny” is insufficient because the request implies that “a controlled study involving live women with the actual TVT device” was somehow *required* prior to marketing

³ See, e.g., *Cohane v. National Collegiate Athletic Ass’n*, 2012 U.S. LEXIS 41217, *6 (W.D.N.Y. March 26, 2012); *Starks-Harris v. Taylor*, 2009 U.S. Dist. LEXIS 16768, *4-5 (N.D. Ind. March 3, 2009); *Bullock v. Kraft Foods, Inc.*, 2011 U.S. Dist. LEXIS 123885, *5 (E.D. Va. Oct. 26, 2011).

⁴ *Havenfield Corp. v. H & R Block, Inc.*, 67 F.R.D. 93, 95 (W.D. Mo. 1973).

⁵ *Bullock*, 2011 U.S. Dist. LEXIS 123885, *4-5.

and selling the product in the United States; thus, if Defendants simply “admit,” it creates the unfair inference that Defendants violated FDA regulations and the 510(k) clearance process.⁶

As for “a controlled study involving live women” versus “a randomized controlled trial,” Defendants understood the latter to be the technical term for the subject matter of the request. “[I]f [a] party [is] unable to agree with the exact wording of the request for admission, it should agree to an alternate wording or stipulation.” *Susko v. City of Weirton*, 2010 U.S. Dist. LEXIS 61617, *6 (N.D. W. Va. June 21, 2010) (quoting *Milgram Food Stores, Inc. v. United States*, 558 F. Supp. 629, 636 (W.D. Mo. 1983)). Where necessary, this is what Defendants have done. In the event Defendants have misunderstood some nuance of this request (or any other), Plaintiffs could have brought that to Defendants’ attention at the required “meet and confer.”

Similarly, Plaintiffs assert that Defendants’ response to RFA No. 108 is “illustrative” of the qualifications they deem unjustified:

REQUEST NO. 108: Admit that the IFU has never stated to physicians that the TVT mesh can become deformed with tension during placement.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 108. Defendants admit that the actual words “TVT mesh can become deformed with tension during placement” are not stated in the IFU. Ethicon selected an appropriate mesh, and provided specific procedural steps for implantation in the IFU to prevent clinically significant deformation that, if properly followed, prevent such an occurrence. Further, TVT employs a sheath to prevent the mesh from clinically significant deformation.

What RFA 108 illustrates, however, is the highly technical medical issues involved in this litigation. There is a difference between clinically significant “deformation” and non-clinically significant “deformation.” Simply admitting or denying this request does not fairly respond to the subject matter of the request and would convey unwarranted, unfair inferences. Denying that the IFU included this warning presents only a sliver of the truth: the exact words

⁶ This unfair inference is also present in RFA No. 2.

did not appear in the IFU because the design of the mesh, the design of the sheath and the specific instructions for implantation (when properly followed) prevent clinically significant “deformation.”⁷

For each RFA where Plaintiffs claim the qualification is unjustified, the same issue exists: each involves a highly technical medical issue where a simple “admit” or “deny” response presents only “half a fact” and standing alone, out of context of the whole truth, would convey an unfair inference. *See Herrera*, 143 F.R.D. at 549; *Diederich*, 132 F.R.D. at 619. These include:

- improper inference that Defendants had no evidence regarding the bi-directional elastic properties of the mesh and its adaptation to various stresses in the body because no human studies with that precise primary endpoint were conducted, despite multiple mechanical and animal studies and years of data establishing these qualities (RFA Nos. 63-65);
- ignoring the distinction between clinically significant “roping” and/or “curling” and non-clinically significant “roping” and/or “curling,” as well as the preemptive steps Ethicon took to prevent the former from occurring; improper inference that all “roping” and/or “curling” is clinically significant (RFA Nos. 66-74, 77-84);
- improper inference that the risks Ethicon warned of did not cover erosion and/or exposure, ignoring that the risk was conveyed to physicians using other language, and ignoring the preemptive steps Ethicon took to prevent it from occurring if the steps for implantation in the IFU were properly followed (RFA Nos. 70-71, 75-76, 82-83, 85-86, 88-93, 98-100, 125, 127, 145, 155, 162-163);
- improper inference that the risks Ethicon warned of did not cover urinary retention, ignoring that the risk was conveyed to physicians using other language, and ignoring the preemptive steps Ethicon took to prevent it from occurring if the steps for implantation in the IFU were properly followed (RFA Nos. 72-74, 80, 84, 125, 127);
- improper inference that the risks Ethicon warned of did not cover encapsulation, and ignoring the preemptive steps Ethicon took to prevent it from occurring if the steps for implantation in the IFU were properly followed (RFA Nos. 88-90, 93, 164);
- improper inference that the mesh has “rough edges” (RFA Nos. 94-95 and 101);

⁷ This unfair inference is also present in RFA Nos. 107.

- improper inference that the risks Ethicon warned of did not cover fraying and/or conditions caused by fraying, and ignoring the preemptive steps Ethicon took to prevent it from occurring if the steps for implantation in the IFU were properly followed (RFA Nos. 96-100, 102-104);
- ignoring that contraction is part of normal wound healing; ignoring the distinction between clinically significant contraction and non-clinically significant contraction, as well as the preemptive steps Ethicon took to prevent it from occurring if the steps for implantation in the IFU were properly followed; improper inference that all contraction is clinically significant (RFA Nos. 109-111, 113-117, 120-122, 126);
- improper inference that that the risks Ethicon warned of did not cover dyspareunia or pain with intercourse, ignoring that the risk was conveyed to physicians using other language, and ignoring the preemptive steps Ethicon took to prevent it from occurring if the steps for implantation in the IFU were properly followed (RFA Nos. 128, 146, 147-148, 156-159);
- improper inference that the risks Ethicon warned of did not cover foreign body response and/or inflammation, ignoring that the risk was conveyed to physicians using other language, and ignoring the preemptive steps Ethicon took to prevent it from occurring if the steps for implantation in the IFU were properly followed (RFA Nos. 129-130, 135-144);
- improper inference drawn from partial statements regarding the results of certain studies involving cancer (RFA Nos. 184-186, 188, 217); and
- improper inference that the risks Ethicon warned of did not cover other miscellaneous warnings, and ignoring the preemptive steps Ethicon took to avoid those events/conditions from occurring if the steps for implantation in the IFU were properly followed (RFA Nos. 128-133, 149-152, 180-182).

The qualifications are *not* “based upon facts and allegations unrelated to the substance of the request.” *See Kelatron v. Marlyn Nutraceuticals*, 2013 U.S. Dist. LEXIS 119590, *10 (D. Utah Aug. 21, 2013); *see generally*, Pl. Mem. [Doc. 1021] at 6-7. Nor are they quibbling over common-sense terms like “policies and procedures.” *See Deya v. Hiawatha Hosp. Ass’n*, 2011 U.S. Dist. LEXIS 44337, *7-8 (D. Kan. April 25, 2011). Rather, the qualifications provided by Defendants “provide clarity and lucidity to the genuineness of the issue” in each request by addressing the part of the “truth” Plaintiffs ignore in their attempt to convey unwarranted and

unfair inferences against Defendants. *Wiwa*, 2009 U.S. Dist. LEXIS 45621, *17. The need for qualifications is particularly acute because many, if not all, of Plaintiffs' requests "involve[] sharply contested issues, or go[] to the heart of [Defendants'] liability." *Id.*

B. Federal Rule of Civil Procedure 36 allows a party to object to part of a request for admission and respond to the non-objectionable portion in accordance with the Rule.

Nothing in Federal Rule of Civil Procedure 36 limits a party to *either* objecting *or* answering a request for admission. "If the objection is only to a portion of the request, the responding party is required to unambiguously answer that portion of the request to which the objection does [not] apply." *Susko v. City of Weirton*, 2010 U.S. Dist. LEXIS 45086, *8-9 (N.D. W. Va. May 7, 2010) (quoting *Henry v. Champlain Enterprises, Inc.* 212 F.R.D. 73, 78 (N.D.N.Y. 2003) (citation omitted)). The RFAs to which Defendants objected were not, for example, requests seeking attorney-client privileged information or trade secrets, where objecting to the entire request with no further response might be appropriate. Rather, these RFAs contained vague, ambiguous, and undefined terms. *See, e.g.*, RFA Nos. 8, 10, 11, 15, 17, 22, 24, 25, 118, 119, 190-199, 201-209, and 211-216. However, once Defendants specified their objection to that portion of the request, they were able to fairly respond to the remaining substance of Plaintiffs' requests. For example:

REQUEST NO. 10: Admit that the TVT mesh marketed and sold in the United States is "heavyweight mesh" as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002), attached hereto.

RESPONSE:

Defendants object to Request No. 10 because "heavyweight mesh" is vague and ambiguous because both meshes tested in the referenced article were used for hernia repair and not for stress urinary incontinence, because there is no medical device industry standard to measure or define "heavyweight mesh," and because the referenced article does not specifically define "heavyweight mesh." Subject to and without waiving this objection, Defendants deny Request No. 10,

except as hereinafter expressly admitted. Defendants admit that PROLENE* mesh used in TVT is heavier in weight than Vypro mesh.

Plaintiffs' request implies that there is defined term in the referenced article when there is not; further, there is no medical device industry standard to measure or define "heavyweight mesh." The objections made, as well as the response to the non-objectionable portion of the request, are appropriate in these circumstances – and such is the case with each of the objections and responses Plaintiffs cite.

C. Defendants' objections based on Plaintiffs' imprecise terminology are well-founded.

As the Court is well-aware, the terminology in the context of medical devices and scientific studies involving those devices is necessarily precise. Plaintiffs' RFAs knowingly used terms for which there is no medical device industry standard or no medical definition. For instance, Plaintiffs' RFAs related to measurement of "pore sizes" of different meshes fail to define a standard for measurement; Plaintiffs also fail to provide a benchmark for the comparative terms used to describe the weight and pore size of different meshes. Similarly, Defendants are unaware of any medical or scientific definition of the terms "high responder"/"low responder" (RFA No. 178), and Plaintiffs' failure to define those terms warrants an objection. Likewise, there is no medical definition for the term "scar-plate" (RFA 193) and, in the absence of any definition provided by Plaintiffs, Defendants' objection is well-taken.

The objectionable size and weight terminology Plaintiffs utilize includes: "average pores" (RFA Nos. 8, 15, 22); "heavyweight meshes" (RFA Nos. 190, 192, 193, 194); "lighter weight mesh" (RFA No. 190); "small pore mesh" (RFA No. 191); "lighter weight, larger pore meshes" (RFA No. 196); "heavyweight, small pore meshes" (RFA Nos. 196, 197, 198); and "meshes with larger pores" (RFA No. 198); and other references to pore sizes (RFA Nos. 8, 15, 22, 190, 191, 192, 195). Because there is no medical industry device standard to measure or define pore sizes

– average or not – or mesh weight, Defendants objections are well-founded. Moreover, the RFAs addressing the weight of the mesh assume some sort of undefined comparison (heavyweight versus lightweight or “lighter weight”) without providing any comparator in the request itself.

Finally, Defendants make clear that they do not measure their mesh products by “pore size,” but rather by courses and wales, an industry standard in textile construction – a fact of which Plaintiffs are well aware as Defendants have produced material specifications for their products in this litigation. If it were truly Plaintiffs’ intention to narrow the issues at trial, they would have crafted RFAs using *that* information instead of playing “fast and loose” with imprecise, undefined terms.

D. There is nothing “vague” or “ambiguous” about the responses against which Plaintiffs lodge such objections.

Plaintiffs argue that Defendants’ responses to RFA Nos. 46-53 and 154 are “vague and ambiguous” – but this is simply not the case. The responses to RFA Nos. 46-49⁸ clearly state that “[d]espite reasonable inquiry, the information known and readily obtainable by Defendants is insufficient to enable them to admit or deny” the request. By way of further response, Defendants then go on to “admit” that “*at present*” they have not identified any TVT marketing materials that include references to the matters about which Plaintiffs inquire. For example:

REQUEST NO. 46: Admit that you never disclosed in any of your TVT marketing materials that include references to Professor Ulmsten or any of his studies, the fact that Professor Ulmsten was your paid consultant.

RESPONSE:

Despite reasonable inquiry, the information known and readily obtainable by Defendants is insufficient to enable them to admit or deny Request No. 46. Defendants admit that, at present, they have not identified any TVT marketing materials that expressly state that Professor Ulmsten was a paid consultant.

⁸ RFA Nos. 46, 47, 48 and 49 are identical except that they address Professor Ulmsten, Professor Nilsson, Professor Rezapour, and Professor Falconer, respectively.

Defendants are aware that they are under a continuing duty to supplement their Responses to Plaintiffs RFAs and, to the extent any further reasonable inquiry of the information known and readily available to them allows them to either admit or deny these requests, they will do so. However, keeping Plaintiffs apprised of what Defendants knew at the time they filed the original answers and objections is in no way “vague” or “ambiguous,” and those responses should not be deemed admitted.

RFA Nos. 50-53⁹ include an improper assumption that the individual relationship between a specified professor and Defendants was, in fact, a “conflict of interest,” when no such conflict of interest existed. Those requests go on to ask Defendants to “admit” that they did not disclose the alleged “conflict of interest” in TVT marketing materials. For example:

REQUEST NO. 50: Admit that you have never disclosed in any of your TVT marketing materials that include references to Professor Ulmsten or any of his studies, the fact that Professor Ulmsten had a conflict of interest due to his relationship with you.

RESPONSE:

Except as hereinafter expressly admitted, Defendants deny Request No. 50. Defendants admit that they have not expressly stated in any TVT marketing materials that there was any “conflict of interest” due to Professor Ulmsten’s relationship with Ethicon or Johnson & Johnson.

Again, there is nothing “vague” or “ambiguous” about this response. Defendants “admit” that no TVT marketing materials expressly state there was a “conflict of interest” but “deny” the rest of the request – i.e., deny that there was any such “conflict of interest” to be disclosed.

Finally, RFA No. 154 and Defendants’ response state:

REQUEST NO. 154: Admit that you never instructed a physician to remove older versions of the TVT brochures from his or her office.

⁹ RFA Nos. 50, 51, 52, and 53 are identical except that they address Professor Ulmsten, Professor Nilsson, Professor Rezapour, and Professor Falconer, respectively.

RESPONSE:

Despite reasonable inquiry, the information known and readily obtainable by Defendants is insufficient to enable them to admit or deny Request No. 154 as stated. Defendants admit that Ethicon did not provide a formal written communication to all customers to remove older patient brochures; however, when Ethicon sales representatives provided new brochures many would have removed old brochures or instructed physicians to use the new brochures.

Like Defendants' responses to RFA Nos. 46-49, Defendants clearly state as allowed by Rule 36 that "[d]espite reasonable inquiry, the information known and readily obtainable by Defendants is insufficient to enable them to admit or deny" the request. And again, keeping Plaintiffs apprised of what Defendants had been able to learn at the time of the response is in no way "vague" or "ambiguous."

Finally, if the Court deems the second portion of these responses superfluous, then it is the *second* portion that should be stricken, leaving Plaintiffs with requests that have neither been admitted nor denied (RFA Nos. 45-49 and 154) or simply denied (RFA Nos. 50-53).

Conclusion

Because Plaintiffs did not comply with this Court's rules and (1) even attempt to meet and confer with Defendants or (2) file the motion in a timely manner, the Court should deny this motion. Alternatively, because Defendants' answers and objections are sufficient and appropriate under Federal Rule of Civil Procedure 36, Plaintiffs' motion to determine the sufficiency of Defendants' responses to Plaintiffs' requests for admission, and any request to deem those requests for admissions admitted, should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on January 23, 2014, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones

Christy D. Jones